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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/087,599

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EXAMINER

VU, QUYNH-NHU HOANG

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/087,599	Applicant(s) CONSTANTZ ET AL.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/12/06 & 12/12/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-54 is/are pending in the application.
- 4a) Of the above claim(s) 35-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Election/Restriction and Amendment and filed on 5/12/06 and 12/12/06 have been entered.

Claims 1-23, 25-34 are present for examination.

Claim 24 is cancelled.

Claims 35-54 are withdrawn.

Election/Restrictions

Applicant's election without traverse of Group I, Species A (Fig. 2), claims 1-23 and 25-34 in the reply filed on 12/12/06 is acknowledged.

Claims 35-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/12/06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-15, 17-21, 28-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz et al. (US 2003/0009132).

Schwartz discloses a device comprising: a fluid delivery element 4 (Fig. 1) or 26 (Fig. 3) or 60(Fig. 15, the elongate member 60 can be used for needle, catheter and similar lumen-defining elongate devices suitable for use in the body, see para [0113])); a compliant porous region 6 (Fig. 1) or 30 (Fig. 3)

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or 66 (Fig. 15) at a distal end of the fluid delivery element (see para (0068)); an aspiration element (para [0068]); the device includes an external energy application element (electrocardiogram, ECG, see Fig. 2 also); the device further comprises a second fluid delivery element 94 or 64 (Figs. 15-16).

Since Applicant does not clearly explain the meaning of the word "complaint". Examiner interprets "complaint" means something easy to flexible or soft. Furthermore, Applicant recites that a porous material include polymeric materials, e.g., plastic such as polyethylene, PTFE, ect, metals, e.g., stainless steel (para [35]). Schwartz discloses that the distal end of catheter is constructed of a porous polymer ([0018]), which is similar material with the Applicant. Therefore, the porous region 6 can be called compliant porous region;

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 16, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al.

Schwartz discloses the invention substantially as claimed. Schwartz does not disclose the device includes sonic energy application. However, it is very well-known in the art to provide the sonic energy (ultrasonic/ultrasound) in the medical art for delivering ultrasound to a target site. The Applicant also admitted the sonic energy application is well-known in the art (see para [46] of the Specification).

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz in view of Hansmann et al.

Schwartz discloses the device as described above in reference to claims 1, 12 and 21, (see rejection above), but fails to disclose that the device has three separate fluid flow paths.

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Hansmann discloses a device for delivering ultrasonic energy and a therapeutic compound from the catheter to the treatment site with three separate fluid flow paths 30.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Schwartz by incorporating the distinct fluid paths of the type taught by Hansmann in order to allow even flow of fluid (col. 10, line 55).

Claims 23, 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. in view of Stevens et al. (US 5,916,193).

Schwartz discloses the device as described above in reference to claim 21, but fails to explicitly disclose an occlusion element.

Stevens et al. discloses a similar device with a plug occlusion element 674; a shunt 686 and a cap 690. See Figs. 4L-M.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Schwartz by incorporating the plug, shunt and cap of the type, as taught by Steven, in order to isolate the region to which the fluid is to be delivered.

Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz in view of Hansmann et al. and Stevens et al.

Schwartz discloses the device as described above in reference to claims 1, 12 and 21, (see rejection above), but fails to disclose that the device has three separate fluid flow paths; a valve; a shunt and a cap element.

Hansmann discloses a device for delivering ultrasonic energy and a therapeutic compound from the catheter to the treatment site with three separate fluid flow paths 30.

Stevens discloses a similar device with a plug occlusion element 674, a shunt 686, and a cap 696 (Figs. 4L-M).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Schwartz by incorporating the plug, shunt and cap of the type, as taught

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by Steven and the distinct fluid paths of the type taught by Hansmann in order to isolate the region to which the fluid to be delivered and to allow even flow of fluid (Hansmann col. 10, line 55).

Regarding claim 34, Schwartz in view of Hansmann and Stevens disclose the invention substantially as claimed. Schwartz in view of Hansmann and Stevens do not disclose the device includes sonic energy application.

However, it is very well-known in the art to provide the sonic energy (ultrasonic/ultrasound) in the medical art for delivering ultrasound to a target site. The Applicant also admitted the sonic energy application is well-known in the art (see para [46] of the Specification).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-23, 25-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Application No. 11/318,049.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of instant claims are fully disclosed and covered by the claims in the copending application claims.

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Response to Arguments

Applicant's arguments with respect to claims 1-23, 25-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763